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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,498	01/16/2004	Melvin Dorin	1754A-008 C1 (81841.0251)	7662
46267	7590	12/23/2005	EXAMINER	
HOGAN & HARTSON LLP 500 S GRAND AVE SUITE 1900 LOS ANGELES, CA 90071			REIFSNYDER, DAVID A	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,498

Applicant(s)

DORIN ET AL.

Examiner

David A. Reifsnyder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,13,14 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,6,9,10 and 46-49 is/are allowed.
- 6) ☒ Claim(s) 1,3,7,8,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/04 6) ☐ Other: _____

DETAILED ACTION

Abstract of the Disclosure

The abstract of the disclosure is objected to because it is too long. The abstract should have between 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. Correction is required. See MPEP § 608.01(b).

Continuing Data

The continuing data in the related-applications section (i.e. page 1, 1st paragraph) of the specification needs to be updated, because U.S. Application Serial No.'s 10/213,018 and 09/607,232 have matured into U.S. Patent No's 6,746,601 B2 and 6,458,067 B1, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishimaru et al.

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Regarding claims 1, 3 and 13; Ishimaru et al. discloses a removable polyolefin polymer liner (64) for a centrifuge container (16) having an interior cavity (54, 56) and an opening, the removable polyolefin polymer liner (64) comprising: a disposable flexible, semi-rigid body with an opening (76) for introducing a sample, wherein the disposable flexible, semi-rigid body of the removable polyolefin polymer liner (64) conforms to the interior cavity of the centrifuge container (16), once inside the centrifuge container (16). (see figs. 2,3 and 5)

Claims 1, 3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenhalgh.

Regarding claims 1, 3 and 14; Greenhalgh discloses a removable liner (20) for a container (10) having an interior cavity and an opening, the removable liner (20) comprising: a disposable flexible, semi-rigid pre-sterilized (col. 2, line 2) body with an opening for introducing a fluid, a plurality of pleated strengthening structures (22) integrally formed on a side wall of the disposable flexible, semi-rigid pre-sterilized (col. 2, line 2) body of the removable liner (20) for strengthening the disposable flexible, semi-rigid pre-sterilized body of the removable liner (20), wherein the disposable flexible, semi-rigid body pre-sterilized body of the removable liner (20) conforms to the interior cavity of the container (10), once inside the container (10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishimaru et al.

Regarding claims 7 and 8; Ishimaru et al. discloses an o-ring for providing a seal between his removable liner and his centrifuge container but fails to disclose that the o-ring is integrally formed with the body of his removable liner. It is considered that it would have been obvious to one having ordinary skill in the art at the time of the

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invention to have made Ishimaru et al.'s o-ring integral with his body of his removable liner for ease of assembly of the o-ring between Ishimaru et al.'s removable liner and his centrifuge container, and to create a good seal between Ishimaru et al.'s removable liner and his centrifuge container. Regarding claim 14: Ishimaru et al. discloses that claimed invention except for his liner being pre-sterilized. It is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention that Ishimaru et al.'s liner be pre-sterilized so that his biological fluids to be separated do not become contaminated.

Allowable Subject Matter

Claims 9, 10, 5, 6 and 46-48 are allowed.

The reason for the allowance of claims 9, 10, 5, 6 and 46-48 can be found on page 8, lines 6-17 of the applicants remarks filed on January 16, 2004.

Response to Arguments

Applicant's arguments filed on January 16, 2004 have been fully considered but in regards to claims 1, 3, 7, 8, 13 and 14 they are not persuasive.

Regarding claims 1, 3, 7, 8, 13 and 14; the applicant argues on page 6 line 21 to page 7, line 7 of his remarks that Ishimaru et al. does not teach or suggest a semi-rigid liner made of a resilient material that is reversibly deformable. Ishimaru et al. teaches on column 3, line 52 to column 4, line 7 a flexible liner (64) that is a semi-rigid liner because the liner (64) flexes when his rotor rotates about a spin axis (102) and when

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the rotor stops rotating the liner (64) returns to its original orientation. See also column 4, lines 37-46.

Regarding claims 1, 3, 7, 8, 13 and 14; the applicant argues on page 7, lines 8-12 of his remarks that Greenhalgh does not teach or suggest a semi-rigid liner made of a resilient material that is reversibly deformable. Greenhalgh teaches on col. 1, lines 20-23 a liner that is a semi-rigid liner because when the liner is placed inside a container, the liner does not conform to the inner contour of the container until the container is filled with liquid. See also column 2, lines 24-32 and column 3, lines 24-33.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dorin et al. 6,746,601 B2 who is the parent of the present application and discloses a removable conformal liner for a centrifuge container.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Reifsnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David A Reifsnyder
Primary Examiner
Art Unit 1723

DAR